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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,688	01/27/2004	Anand Baichwal	540.91195CP5	2079

23280 7590 10/02/2006

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,688	BAICHWAL, ANAND	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,10,14-16 and 18-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10,14-16 and 18-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner noticed in the responses and amendments filed by applicant that the wrong application number was in the upper left hand corner of the documents the application number being prosecuted is 10/766,688 **not** 10/731,859. The amendment to the claims filed 09/06/2006 has been entered. Any previous rejection from the office action dated 06/01/2006 not addressed within this office action has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7,9,10,14-16 and 18-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al. (US 5,128,143) in view of Oshlack et al. (US 5,472,712 received benefit of priority date from US 5,273,760 12/24/1991) and in further

view of Colombo (US 4,839,177), for the reasons set forth in the office action mailed 6/29/2004.

Applicant's arguments filed 06/01/2006 have been fully considered but they are not persuasive.

Applicant asserts that the teachings of the '143 (Baichwal) patent are not properly combinable with the teachings of the '712 (Oshlack) patent and there is no motivation to combine because the '143 patent is directed to a free-flowing directly compressible sustained release excipient and a tablet formulation comprising the sustained release excipient and an active agent while the '712 patent is directed to controlled release substrates, wherein the active agent substrate(s) such as a tablet, microsphere, pellet or other multi-particulate system is are coated with an aqueous dispersion of a hydrophobic polymer (ethylcellulose), wherein the controlled release is caused by a coating of the substrate with the hydrophobic polymer and not by mixing together the active agent and a sustained release excipient and tabulating the mixture into tablets as disclosed in the '143 patent. Applicant then asserts that even if motivation were provided to one skilled in the art to combine the teachings of the '712 patent with the '143 patent the results would not be the dosage forms claimed in the present invention but instead would be a dosage form comprising active agent substrates coated with a controlled release coating comprising an sustained release excipient comprising a gelling agent, an ionizable gel strength enhancing agent and an inert diluent.

The relevance of this assertion is unclear. Clearly, both of the patents are related in that they both disclose controlled or sustained release formulations. Baichwal discloses a tablet that comprises all of applicants claimed invention except for the use of a solid support, while Oshlack discloses a substrate that can be a tablet that is coated with a hydrophobic polymer (ethylcellulose), thus by combining the disclosure of Baichwal with Oshlack one skilled in the art could make, on their own, the same invention as applicants, that is a sustained release tablet as claimed in claim 1 from Baichwal with the solid support comprised of a hydrophobic polymer disclosed in Oshlack. It would have been obvious to combine the above documents because there is always motivation to enhance the controlled release of a medicament, so one skilled in the art could foresee that by combining the controlled release tablet in Baichwal and the controlled release coating in Oshlack the release rate of the dosage form could be further enhanced or modified.

Applicant further asserts that there is no motivation to combine the '177 patent (Colombo) for its disclosure of a solid support with '143 and '712.

The relevance of this assertion is unclear. All of the patents are related in that they all disclose controlled or sustained release formulations. Baichwal discloses a tablet that comprises all of applicants claimed invention except for the use of a solid support, while Oshlack discloses a substrate that can be a tablet that is coated with a hydrophobic polymer (ethylcellulose) and Colombo discloses a support platform applied to a deposit core comprising the active substance and having a geometric form, the deposit-core can generally have a geometric form similar to a cylindrical tablet with flat,

convex or concave faces, thus by combining the disclosures above one skilled in the art could make, on their own, the same invention as applicants, that is a sustained release tablet as claimed in claim 1 with a solid support comprised of a hydrophobic polymer. It would have been obvious to combine the above documents because there is always motivation to enhance the controlled release of a medicament, so one skilled in the art could foresee that by combining the controlled release tablet in Baichwal and the controlled release coatings or solid support in Oshlack and Colombo the release rate of the dosage form could be further enhanced or modified.

Double Patenting

Claims 1-7,9,10,14-16 and 18-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,048,548 in view of Colombo (US 4,839,177).

Claims 1-7,9,10,14-16 and 18-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,709,677 B2 in view of Colombo (US 4,839,177).

Since the applicant did not disclose a terminal disclosure and the case is not in condition for allowance the double patenting rejection from the previous office action dated 06/01/2006 still stands.

Conclusion

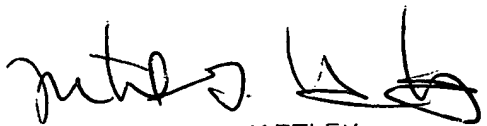
No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (572) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (572) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER